

§ 74.1260

2',4',5'-tribromofluorescein, not less than 30 percent and not more than 40 percent.
2',4',5',7'-tetrabromofluorescein, not more than 10 percent.
Sum of 2',4'-dibromofluorescein and 2',5'-dibromofluorescein, not more than 2 percent.
4'-Bromofluorescein, not more than 2 percent.
Fluorescein, not more than 1 percent.
Phthalic acid, not more than 1 percent.
2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Brominated resorcinol, not more than 0.4 percent.
Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.
Insoluble matter (alkaline solution), not more than 0.3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested drugs in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used in externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 44635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.1260 D&C Orange No. 10.

(a) *Identity.* (1) The color additive D&C Orange No. 10 is a mixture consisting principally of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein, and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 10 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

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(b) *Specifications.* D&C Orange No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-[3',5'-Diiodo-2',4'-dihydroxybenzoyl] benzoic acid, not more than 0.5 percent.
Fluorescein, not more than 1 percent.
4'-Iodofluorescein, not more than 3 percent.
2',4'-Diiodofluorescein and 2',5'-diiodofluorescein, not more than 2 percent.
2',4',5'-Triiodofluorescein, not more than 35 percent.
2',4',5',7'-Tetraiodofluorescein, not more than 10 percent.
4',5'-Diiodofluorescein, not less than 60 percent and not more than 95 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

§ 74.1261 D&C Orange No. 11.

(a) *Identity.* (1) The color additive D&C Orange No. 11 is a mixture consisting principally of the disodium salts of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 11 may contain only those diluents listed in this subpart as safe and suitable for use